REMARKS

Claims 1-32 are pending in the application. Claims 2, 4, 12, 25-28 and 31 are cancelled herein. The claims have been amended to replace the term "biopolymer" with "nucleic acid" as disclosed in original claim 2 and throughout the specification. The claims have also been amended to define the magnetic particles as "silica-coated magnetic particles" in accordance with the specification at page 8, lines 30-34. The additive in claim 1 has been defined as being "hydratable" as disclosed at page 7, lines 1-2. Claim 1 has also been amended to recite a Markush group of additives, as described at page 7, lines 1-7. The concentration of additives in claim 1 is restricted to be in the range of from 2% to 7% (w/v) which corresponds to original claim 18. Claim 1 has also been amended to recite the concentration of salt in the aqueous solution, as defined in the paragraph bridging pages 10 and 11. The phrase "form a complex" in claim 1 has been replaced with "to adhere, reversibly bind or absorb to the particles of step (a). This amendment is supported by the disclosure at page 9, lines 28-31 (reversible binding) and page 5, lines 23-27 (adhesion). Claim 1 was further amended to clarify that the magnetic beads do not cluster in the presence of the hydratable additive and aqueous solution, *i.e.*, throughout the entirety of the process.

Claim 3 has been amended to define the nucleic acid as DNA, RNA or a RNA/DNA hybrid, as described at page 8, first full paragraph.

The remaining claims are adapted to the amendments discussed above.

The specification has been amended to correct typographical errors. The Abstract has been replaced.

No new matter has been added by these amendments to the claims, specification and Abstract.

I. Rejection Under 35 U.S.C. § 101

Claims 25-28 and 30 are rejected under 35 U.S.C. § 101. It is respectfully submitted that cancellation of these claims renders this ground of rejection moot.

II. Rejection of Claims 1-32 Under 35 U.S.C. § 112, First Paragraph

Claims 1-32 are rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter that was not described in the specification in such a manner as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time of filing.

This rejection is respectfully traversed as follows.

The Office Action states that the specification only exemplifies isolation of DNA by the claimed process and has not described how to isolate other biopolymers. However, the claims have been amended to identify the biopolymers that are isolated using the claimed process as DNA, RNA and hybrids thereof. Isolation of nucleic acids is well known in the art. Moreover, DNA and RNA are structurally very similar and share similar properties. One of skill in the art would recognize from exemplification of the process using DNA, that the same process can be used to isolate RNA and hybrids of the two nucleic acid forms.

Accordingly, the rejection of claims 1-32 under 35 U.S.C. § 112, first paragraph is respectfully traversed.

III. Rejection of Claims 1-32 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-32 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The claim terms "biopolymer," "magnetic beads" and "additive" are found to be indefinite. The phrase "to form a complex" is objected to as being inaccurate to describe the claimed interaction. The description of washing/solution steps was objected to; the wherein

clause was objected to; the phrase "an automated process" was objected to; and use of the phrase "silica magnetic beads" was objected to.

This rejection is respectfully traversed as follows.

The claims have been amended to more clearly define the claimed invention. In particular, the terms "biopolymer," magnetic beads," "to form a complex" and "silica magnetic beads" have been defined with more particularity. The claims have been amended to recite separate washing and elution steps. In regards to the term "automated process" it is respectfully submitted that the metes and bounds of claim 24 in which the phrase arises are quite clear. Claim 24 further defines the process of claim 1 as an automated process. the specification includes several examples in which the claimed nucleic acid isolation process is fully automated using a robotic system to carry out the claim steps. Such robotic, automated systems are known in the art to be applicable to nucleic acid and other biopolymer isolation processes.

The Office Action concludes that the wherein clause in claim 1 does not properly refer back to the essential features of the invention and as such, will not be given patentable weight. It is respectfully submitted that the clause clearly makes reference to each of the steps of the claimed process by referring to the entirety of the performance of the process. However, in order to expedite prosecution, Applicants have amended the claims to make a specific reference to a lack of clustering in the presence of the aqueous solution and hydratable additive.

It is respectfully submitted that the claims, as amended, addresss and traverse the various grounds of rejection. Accordingly, the rejection of claims 1-32 under 35 U.S.C. § 112, second paragraph is respectfully traversed.

IV. Rejection of Claims 1-32 Under 35 U.S.C. § 103(a) Over Hawkins in View of Smith

Claims 1-32 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over Hawkins in view of Smith. The Office Action found that Hawkins teaches a process for isolating DNA using many of the features of the claimed method, but does not disclose the use of silica coated magnetic particles. Smith is relied on as teaching use of silica coated magnetic particles as absorbent in a DNA isolation process. The Office Action concludes that it would have been obvious to have substituted Smith's silica-coated particles for Hawkins' carboxyl-coated magnetic particles in the course of routine optimization. The Office Action also concludes that it would have been obvious to optimize the concentrations of salt and polyalkylene glycol.

Applicant respectfully disagrees.

It was known to those of skill in the art at the time of the invention that one of the technical problems associated with the use of magnetic particles, such as silica-coated particles, and in particular with automated separation processes using magnetic beads, was clumping of the beads, leading to significantly decreased yield of separation product. The present invention addresses this technical problem and results in significantly reduced magnetic bead clustering and increased yield of separation products through the use of silica-coated particles in the presence of a salt and a further defined additive. As a result of the reduced magnetic bead clumping, the claimed method can be fully automated. Examples 1 and 2 in the specification demonstrate the surprising results obtained with the claimed process.

In contrast, Hawkins describes the use of polyalkylene glycol and a salt for purifying and isolating DNA. However, the combination of polyalkylene glycol and salt is used as a binding buffer for a specific kind of magnetic particles, namely carboxyl-coated magnetic particles. This

is obvious from examples 1 and 6 of the cited reference, but also, for example, from column 2, lines 39-43, column 5, lines 28-35 and column 8, lines 58-62. In those paragraphs it is indicated that a specific concentration of salt and polyalkylene glycol is required to achieve a binding of DNA to the specified, functional group-coated magnetic particles. The problem of clustering of the magnetic particles after the DNA has bound is not mentioned in this reference. Consequently, the use of a combination of salt and polyalkylene glycol by Hawkins has a completely different purpose than in the present method. Hawkins does not suggest the effect of salt and the claimed additive on the clumping properties of any type of magnetic beads.

The above is also strengthened by the concentrations of polyalkylene glycol or additive, respectively, used by Hawkins. The typical range of polyethylene glycol used in Hawkins' method is from about 7 to about 13% (see col. 2, l. 47/48 and col. 5, l. 62-65). In the latter citation it is even pointed out that all deviations from a concentration of 10% result in decreased yields. In contrast in the present method the concentration of additive preferably ranges from 2 to 7%.

Since there is no suggestion in Hawkins that the combination of salt and polyalkylene glycol can be used for reasons other than inducing the binding of DNA to a very specific kind of magnetic bead surface, the skilled practitioner would not have been motivated to replace Hawkins' carboxyl-coated magnetic particles with different, *i.e.*, silica-coated, magnetic particles to solve the problem underlying the present invention. In fact, as discussed above, Hawkins does not even discuss the problem of particle clumping. Thus, the results obtained in the present method, *i.e.*, reduced particle clumping and consequent increased yield of isolated nucleic acids (as shown in Examples 1 and 2), are unexpected in view of the combination of Hawkins and Smith.

Accordingly, the rejection of claims 1-32 under 35 U.S.C. § 103(a) over Hawkins in view of Smith is respectfully traversed.

It is respectfully submitted that the present application, as amended above, is in condition for allowance, an early notification thereof being earnestly solicited.

To the extent necessary, Applicants petition for an extension of time under 37 C.F.R. 1.136. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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